1639

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---|---|---|
| In re Application of: | ) | Art Unit: 1639 |
| FOWLKES, et al. | ) | Examiner: WESSENDORF, Teresa |
| Serial No.: 09/050,359 | ) | Washington, D.C. |
| Filed: March 31, 1998 | ) | October 8, 2003 |
| For: IDENTIFICATION OF DRUGS USING COMPLEMENTARY COMBINATORY LIBRARIES | ) | Docket No.: FOWLKES=4B |
| | ) | Confirmation No.: 6741 |

**RESPONSE TO NOTICE TO COMPLY AND SUBMISSION OF SUBSTITUTE SPECIFICATION**

U.S. Patent and Trademark Office
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Arlington, Virginia 22202

S i r :

1. The Examiner takes the position that our July 13, 1998 sequence listing submission is defective because

(1) we state that the paper copy and the CRF are "believed to be identical", and we must instead state that they "are identical".

(2) the sequence listing omits sequences in [sic] Tables 1 and 2, page 60. (The tables are actually A-1 and A-2.)

(3) the amendment amends so many paragraphs that it would be onerous to enter them individually, hence, we are required to put them into a substitute specification.

2. The propriety of the prior statement is moot as a substitute paper copy and CRF are submitted herewith, for the reasons set forth in section 5. A new statement, compliant with 37 CFR §§1.821 et seq., is incorporated into this response as section 9.

3. Only one of the sequences on page 60 actually qualifies as a sequence under the rules. The rules say that the amino acid sequence must comprise at least four specified amino acids; an "X" does not qualify. So the only listable sequence is $X_6$ PXPPXPX$_2$, which has four prolines. This sequence appeared previously on page 58, line 18, and it was given SEQ ID NO:14. Accordingly, we have amended original page 60 to refer (at both places) to SEQ ID NO:14; there is no new sequence to list.

4. 37 CFR §1.125(a) gives the Examiner the right to require a substitute specification if the number or nature of the amendments renders it difficult to consider the application, or to arrange the papers for printing or copying. Without conceding that this standard is satisfied, Applicants are nonetheless willing to submit a substitute specification.

There is some question as to the proper formulation of the substitute specification. For example, it is unclear whether the required substitute specification is to include the claims. Since the amendment which was refused entry did not amend any claims, our presumption is is that the requirement is directed to the specification in the narrower sense of that term, i.e., the disclosure which precedes but does not include the claims.

Next, there is the issue of how to show the amendments previously made in this case. According to our records the following amendments have been filed:

| | |
|---|---|
| July 14, 1998 | (added SEQ ID NOs) |
| September 29, 1999 | (amended claims only) |
| May 24, 2000 | (amended claims only) |
| September 8, 2000 | (corrected sequence listing) |
| March 28, 2001 | (amended pp. 10, 25, 91, 103; and various claims) |

| | |
|---|---|
| January 18, 2002 | (after final amendment to p. 10 of spec., and various claims; not entered) |
| March 14, 2002 | (amendment to p. 10 and various claims, accompanying RCE) |
| May 15, 2002 | (corrected sequence 118, added sequences 119-120, and conformed spec.) |
| December 4, 2002 | (amended claims only) |

The status of the May 15, 2002 amendment is unclear, as it presupposed entry of the July 13, 1998 amendment.

We believe that the "immediate prior version of the specification of record" referred to by 37 CFR §1.125(c) is the specification as filed on March 31, 1998, as no substitute specification as previously been filed.

If so, then the substitute specification must not only incorporate the amendments of March 28, 2001, March 14, 2002, and May 15, 2002, it must also represent them as changed text in the "mark-up" version of the substitute specification. We have done so here.

We further believe that we are at liberty under 37 CFR §1.121(b)(4) to incorporate the amendments in the July 18, 1998 amendment (belatedly unentered), and, since it was not entered, we are at liberty to omit any amendment made therein which we no longer deem to be appropriate.

Finally, we believe we are at liberty to make additional amendments which do not add new matter, that have not been made previously, since 37 CFR §1.121(b)(4) says that amendments to the specification, other than the claims may be made by presenting an instruction to replace the specification together with a substitute specification in compliance with 37 CFR 1.125.

5. In the course of reviewing the original specification

and the amendment history, we noted several errors previously overlooked by us as well as by the Examiner's Notice to Comply:

(1) there was an error in SEQ ID NO:19; it mistakenly included the "X10C" as part of the sequence when this merely identified the library.

(2) the consensus sequences at page 90 line 39 and page 91 line 6 were not included in the sequence listing (they are now SEQ ID NOs:169 and 170).

(3) on page 94, line 5 of the original specification, "DNA" should be "AA".

(4) on page 94, line 22 thereof, there is a partial consensus sequence, which we now identify as AAs 2-9 of SEQ ID NO:47.

(5) there was an error in SEQ ID NO:62.

(6) on original page 137, the HCMV UL44 consensus sequence was misinterpreted as four distinct sequences, numbered 168-171 in the unentered 1998 amendment. The substitute sequence listing presents this correctly as one sequence, represented as ID 168.

(7) also on that page, there are several sequences which were overlooked when the sequence listing was prepared. These have been added to the sequence listing and as a result the corresponding page in the substitute specification refers to SEQ ID NOs:168-179. It should be noted that some sequences are exempt from the sequence listing requirement because they include fewer than four specifically defined amino acids, see 37 CFR §1.821(a).

6. We hereby request replacement of the specification, other than the claims, with the enclosed substitute specification. The latter is submitted as both a clean copy and

a mark-up copy, pursuant to 37 CFR §1.125(c).

7. Applicants hereby submit the following:

a paper copy of a "Sequence Listing", complying with §1.821(c), to be incorporated into the specification as directed above;

the Sequence Listing in computer readable form, complying with §1.821(e) and §1.824, including, if an amendment to the paper copy is submitted, all previously submitted data with the amendment incorporated therein.

8. The description has been amended to comply with §1.821(d).

9. The undersigned attorney or agent hereby states as follows:

(a) this submission does not include new matter [§1.821(g)];

(b) the contents of the paper copy (as amended, if applicable) and the computer readable form of the Sequence Listing, are the same [§1.821(f) and §1.825(b)];

(c) if the paper copy has been amended, the amendment is supported by the specification and does include new matter [§1.825(a)]; and

(d) if the computer readable form submitted herewith is a substitute for a form found upon receipt by the PTO to be damaged or unreadable, that the substitute data is identical to that originally filed [§1.825(d)].

10. Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

The Examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

11. The original specification contained underlined text. The rules do not state how to differentiate the use of

underlining to show inserted text from the use of underlining in original text. To avoid ambiguity, we have highlighted all changes in the marked-up text.

12. In certain of the sequences reciting "Xaa", we identify Xaa as meaning "any naturally occurring amino acid", based on page 25, line 28. However, it is noted that at page 25, lines 19-21, we say that "the amino acids are not limited to the naturally occurring amino acids", and the wording of the sequence listing should not be construed as an implied limitation of the disclosure or claims.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: _____
Iver P. Cooper
Reg. No. 28,005

Enclosures
-Notice to Comply
-Substitute Specification (clean copy)
-Substitute Specification (markup copy)
-Substitute Sequence Listing (Paper and CRF)

624 Ninth Street, N.W.
Washington, D.C. 20001
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/050,359 | 03/31/1998 | DANA M. FOWLKES | FOWLKES-4B ✓ | 6741 |

1444 7590 09/08/2003

BROWDY AND NEIMARK, P.L.L.C.
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WASHINGTON, DC 20001-5303

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| EXAMINER |
|---|
| WESSENDORF, TERESA D |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1639 | 35 |

DATE MAILED: 09/08/2003

DOCKETED
10582003

Please find below and/or attached an Office communication concerning this application or proceeding.

1 mo RESTRICTION - 08OC2003

RECEIVED
SEP 10
BROWDY AND NEIMARK
WASH. D.C. 20001-5303

PTO-90C (Rev. 07-01)

| Office Action Summary | Application No. 09/050,359 | Applicant(s) FOWLKES ET AL. |
|---|---|---|
| | Examiner T. D. Wessendorf | Art Unit 1639 |



*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

**DETAILED ACTION**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

***Response to Arguments***

In response to the notice to comply with the sequence rules (paper 28), mailed July 25, 2002, applicants requested to vacate said notice. Applicants argue that on May 15, 2002 an amendment that amended page 121 of the specification to more clearly identify Seq. ID. Nos. 118-120 and provided a substitute page 167 for the sequence listing. All of the pages 94, 97 etc. in the July notice have been addressed.

In response, a review of the July 13, 1998 (paper 4a) reveals the following deficiencies:

1. The statement that the contents of the paper copy and the computer readable form of the sequence listing are ***believed*** to be the same is incorrect. They should be identical and not believed to be identical.

2. The amendment failed to include the other sequences recited in other sections of the specification. E.g., in Tables 1 and 2, page 60. Applicants are further requested to check for other sequences in the specification that have not been assigned a Seq. ID. No. and ensure that all of the sequences in the specification are in the CRF.

3. The amendment on July 13, 1998 requesting amendment to the specification by adding Sequence ID. Nos. to the different sequences regretfully has not been entered since they are too numerous to enter individually. It is requested that applicants provide a substitute specification since the amendments would be too numerous to enter individually.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
September 6, 2003